

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-750V

Dated: July 10, 2017

Not for Publication

PANAGOULA E. BEKIARIS,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Motion for discovery denied

ORDER¹

On August 19, 2014, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10–34 (2012), alleging that human papillomavirus (“HPV” or “Gardasil”) she received on August 25, 2011, caused her an intense skin reaction to her sweat and to soap; hyperactivity; anxiety; allergy; and permanent disfigurement (rashes). Pet. Preamble.

Petitioner filed an affidavit on July 24, 2015 (without giving it an exhibit number). She states that after her third Gardasil vaccination, she has had hypersensitivity to a variety of irritants, including but not limited to her own sweat, chlorine, most soaps, exposure to hot water, lotions, body creams, fragranced laundry detergents, and fabric softeners. Affid. at 1-2. She also states that as a result of her alleged reaction, she has panic attacks, increased obsessive

¹ Because this unpublished order contains a reasoned explanation for the special master’s action in this case, the special master intends to post this unpublished order on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document’s disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall redact such material from public access.

tendencies, and general anxiety. Id. at 2. She states that her alleged reaction has limited her activities, such as walking in the street when it is raining, sweating from hot weather or physical activity, taking showers, and trying on clothes. Id.

On July 7, 2017, petitioner moved for discovery of samples of HPV vaccine used in 2011 because, subsequent to that time, the formula for HPV had changed. Mot. at 3. In addition, petitioner seeks chemical and clinical facts/ notes regarding the former formulation of Gardasil and subsequent formulations; information regarding the changes; and any further information that would assist clinical testing of petitioner. Id.

Petitioner's motion is **DENIED**.

FACTS

Pre-vaccination records

On March 2, 2009, petitioner saw Dr. Patricia Stec, complaining of a runny nose, stuffy nose, coughing, headache, dizziness for 10 days, and anxiety. Med. recs. Ex. 3, at 24.

On July 5, 2010, petitioner saw her doctor because she noticed she was unable fully to extend her arms past 170 degrees bilaterally in cheerleading. Id. She received her first Gardasil vaccination. Id.

On October 16, 2010, petitioner returned to her doctor for her second Gardasil vaccination. Id. She said she felt dizzy after her last vaccination but recovered quickly and felt good afterwards.

Post-Vaccination Records

On August 25, 2011, petitioner received her third Gardasil vaccination. Med. recs. Ex. 3, at 20.

On August 26, 2011, petitioner telephoned Dr. Frank Roemisch and said she had transient urticaria (hives) the prior night, which was eight hours after Gardasil and when petitioner was very stressed regarding time constraints to do her homework. Med. recs. Ex. 5, at 36. Petitioner's urticaria was resolved with Benadryl taken the prior night and repeated that morning. She did not have systemic symptoms. Id.

On August 27, 2011, petitioner telephoned Dr. Roemisch and said her hives relapsed without systemic symptoms. Id. Dr. Roemisch said to take a cool shower and use Benadryl. She was to call on August 29, 2011 or as needed if she had any new or increased symptoms. She was to start a trigger diary. Id.

On October 8, 2011, petitioner saw Dr. Roemisch, complaining of a body rash and severe pruritis (itching) since August 26, 2011, especially on her upper body and arms. Med. recs. Ex. 3, at 25. Benadryl helped, but made her drowsy. She had an increase in pruritis after gym class. Id. On physical examination, petitioner had generalized urticaria with some minor excoriations. Med. recs. Ex. 5, at 37. Dr. Roemisch prescribed Prednisone 20 mg. If petitioner's symptoms increased or persisted, she was to use Xyzal² 5 mg. and see an allergist. Id.

On October 15, 2011, petitioner telephoned Dr. Roemisch and said her pruritis decreased, she was off Prednisone, and she did not use Xyzal. Id.

On November 1, 2011, petitioner saw LPN Reyna Garcia, who works with Dr. Stec. Id. at 33. Petitioner thought she might have scratched her eye. On examination, petitioner was noted to have moderate inflammatory acne on her face for which LPN Garcia prescribed Atralin 0.05% gel. Id.

On April 19, 2012, petitioner telephoned Dr. Roemisch, complaining of pruritus and rashes with multiple lotions and exercise. Id. at 37. She told Dr. Roemisch that Xyzal was too strong. Benadryl was effective but did not last six hours. Petitioner had not seen an allergist because she had not found a Greek allergist and did not have insurance. Dr. Roemisch prescribed Claritin 5 mg. If that did not work, she should try Singulair, and if that failed, she consider adding a H₂ blocker. He said not to use the gym for two months. Id.

On April 17, 2013, petitioner saw Dr. Vassilios Dimitropoulos, a dermatologist, who diagnosed her with acne vulgaris on her face, chest, and back, post-inflammatory hyperpigmentation, and xerosis (abnormally dry skin). Med. recs. Ex. 2, at 14. Petitioner had had acne for six years. Id. (This would put onset of her acne in 2007, four years before her third HPV vaccination.) On physical examination, petitioner had numerous erythematous papules, rare pustules, multiple excoriations, and numerous open and closed comedones.³ Id. at 15. She had many erythematous inflammatory stains. Id. Dr. Dimitropoulos prescribed Minocycline⁴ 100mg. and Tretinoin⁵ 0.025% cream. Id. at 16.

² Xyzal is "trademark for a preparation of levocetirizine dihydrochloride." Dorland's Illustrated Medical Dictionary 2088 (32nd ed. 2012) (hereinafter, "Dorland's"). Levocetirizine dihydrochloride is "a histamine H₁-receptor antagonist used in treatment of allergic rhinitis and chronic idiopathic urticaria" Dorland's at 1032.

³ Comedones are the plural of "comedo." A comedo is a "noninflammatory lesion of acne vulgaris and a few other conditions, consisting of a plug of keratin and sebum within the dilated orifice of a hair follicle; it usually contains bacteria" Dorland's at 390.

⁴ Minocycline is "a semisynthetic broad-spectrum antibiotic of the tetracycline group." Dorland's at 1168.

⁵ Tretinoin is "all-*trans*-retinoic acid, applied topically in the treatment of acne vulgaris" Dorland's at 1959.

On June 19, 2013, petitioner returned to Dr. Dimitropoulos. Id. at 10. Her acne was not itching, painful, or burning. It was localized to her face. Id.

On August 14, 2013, petitioner returned to Dr. Dimitropoulos. Id. at 1. He diagnosed her with improving acne vulgaris and post-inflammatory hyperpigmentation. Id. at 5. Petitioner had an allergic reaction to Cefuroxime⁶ in the form of a rash. Id. at 2.

On February 5, 2014, petitioner returned to Dr. Dimitropoulos. Id. at 6. Her acne was mild, localized to her face, and characterized by blackheads. It did not itch, and was not painful or burning. Id.

On January 7, 2015, petitioner returned to Dr. Dimitropoulos. Med. recs. Ex. 4, at 27. She had facial acne, dermatographism⁷ on her arms, post-inflammatory hyperpigmentation, photodamage, and lentigos.⁸ Id. Dr. Dimitropoulos discussed petitioner seeing an immunologist and allergist. Id.

These are all the medical records petitioner filed. She did not file any medical records from an immunologist or allergist. She did not file any medical records from a neurologist, psychologist, or psychiatrist supporting her allegations that HPV vaccine caused her anxiety and panic attacks.

Petitioner's attorney has used the excuse that he cannot obtain medical records from petitioner because she has been in Greece for years. According to petitioner's attorney during a telephonic status conference on October 14, 2015, petitioner does not see a doctor in Greece. On April 7, 2016, petitioner's attorney told the undersigned during a telephonic status conference that petitioner was seeking medical care in Greece.

On May 17, 2016, petitioner's attorney told the undersigned during a telephonic status conference that petitioner saw an immunologist and allergist Dr. Ioannis Moissidis, in Greece, who would write a report in English.

On July 14, 2016, petitioner's attorney told the undersigned during a telephonic status conference that Dr. Moissidis never sent his medical records or report to petitioner's attorney. According to petitioner's attorney, Dr. Moissidis wants to do advanced allergy tests on

⁶ Cefuroxime is "a synthetic, broad-spectrum β -lactase-resistant, second-generation cephalosporin effective against a wide range of gram-positive and gram-negative bacteria." Dorland's at 312.

⁷ Dermatographism also known as dermographism is "a type of physical urticaria in which moderately firm stroking or scratching of the skin with a dull instrument produces a wheal with a red flare on each side." Dorland's at 499.

⁸ Lentigo is "a small, flat, tan to dark brown or black, macular melanosis on the skin; it resembles a freckle clinically but is histologically distinct" Dorland's at 1022.

petitioner. He wants to obtain the 2011 version of HPV vaccine because there was a subsequent version of HPV vaccine.

On July 14, 2016, the undersigned issued an Order giving petitioner one year to file the expert report of Dr. Ioannis Moissides. Petitioner has yet to file this expert report one year later.

On July 7, 2017, almost one year after the above Order, petitioner moved for discovery from Merck for samples of 2011 HPV vaccine and various other materials.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen v. Sec’y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]” the logical sequence being supported by “reputable medical or scientific explanation[,]” i.e., “evidence in the form of scientific studies or expert medical testimony[.]”

Althen, 418 F.3d at 1278.

Without more, “evidence showing an absence of other causes does not meet petitioners’ affirmative duty to show actual or legal causation.” Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for HPV vaccination, she would not have had urticaria, rashes, acne vulgaris, anxiety, and panic attacks, but also that the vaccine was a substantial factor in causing her urticarial, rashes, acne vulgaris, anxiety, and panic attacks. Shyface v. Sec’y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Vaccine Act does not permit the undersigned to rule for petitioner based on her claims alone, “unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1). Although petitioner’s earlier medical records support a post-HPV vaccine complaint of urticaria and rashes, timing is not sufficient to prove causation. Moreover, she would have to prove that urticaria and rashes related to her vaccination lasted more than six months. 42 U.S.C. § 300aa-11(c)(1)(D)(i). Her dermatology records from Dr. Dimitropoulos refer mostly to petitioner’s having acne vulgaris, not to urticaria and rashes. In 2013, he notes the onset of her acne vulgaris was six years earlier, or 2007 (four years before her third HPV vaccination).

Petitioner has never filed an expert report in support of her allegations, despite the passage of three years. Now, instead of filing an expert report (for which the undersigned gave her a deadline of one year), she wants to obtain samples of 2011 HPV vaccine and data from the vaccine manufacturer Merck. The motion for discovery is another of petitioner's numerous efforts to delay resolution of this case by failing to file medical records and a medical expert report.

Applicable Legal Standard for Discovery

Discovery is not a matter of right in the Vaccine Program. The Vaccine Act, 42 U.S.C. § 300aa-12(d)(3)(B), outlines a special master's authority to direct discovery:

(B) In conducting a proceeding on a petition a special master—

- (i) may require such evidence as may be reasonable and necessary,
- (ii) may require the submission of such information as may be reasonable and necessary,
- (iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,
- (iv) shall afford all interested persons an opportunity to submit relevant written information—. . . and
- (v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

Thus, the plain language of the statute indicates that the special master may require discovery of evidence that is "reasonable and necessary" to the proceedings in a case. "Reasonable and necessary" has been interpreted to mean that:

the special master should require production if the master concludes that, given the overall context of the factual issues to be decided by the master, he or she could not make a *fair and well-informed* ruling on those factual issues without the requested material. Requiring the requested testimony or document production must also be "reasonable" under all the circumstances, which means that the special master must consider the *burden* on the party who would be required to testify or produce documents. That is, the importance of the requested material for purposes of the special master's ruling must be balanced against the burden on the producing party.

In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, 2004 WL 1660351, at *9 (Fed. Cl. Spec. Mstr. July 16, 2004) (emphasis in original) (hereinafter “Omnibus Autism Proceeding”).

Special masters have generally refrained from granting extensive discovery. See Gomez v. Sec’y of HHS, No. 15-160V, 2015 WL 9597899 (Fed. Cl. Spec. Mstr. Dec. 15, 2015) (Special Master Millman denied motion for discovery from Merck regarding production, testing, and safety of Gardasil); Halverson v. Sec’y of HHS, No. 15-227V, 2015 WL 7445510 (Fed. Cl. Spec. Mstr. Oct. 29, 2015) (Special Master Roth denied motion for discovery from Sanofi Pasteur of human and animal data, dose-response curves, and adverse events to flu vaccine); Phillips-DeLoatch, No. 09-171V, 2015 WL 1950107 (Fed. Cl. Spec. Mstr. Apr. 9, 2015) (Special Master Millman denied motion for discovery from Merck of any reports of sudden death occurring after Gardasil vaccination, and any papers, reports, or memoranda discussing a possible biological mechanism for Gardasil causing or triggering sudden death); In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, 2007 WL 1983780 (Fed. Cl. Spec. Mstr. May 25, 2007) (three special masters denied motion for discovery of vaccine safety information held by the Vaccine Safety Datalink Project); Werderitsh v. Sec’y of HHS, No. 99-319V, 2005 WL 3320041, at *4-5 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (former-Special Master Sweeney denied petitioner’s request for access to information from the Vaccine Adverse Event Reporting System); Schneider v. Sec’y of HHS, No. 99-160V, 2005 WL 318697 (Fed. Cl. Spec. Mstr. Feb. 1, 2005), aff’d, 64 Fed. Cl. 742, 746 (2005) (former-Special Master Edwards denied discovery of the vaccine manufacturer’s information about the manufacturing and testing of hepatitis B vaccine); Omnibus Autism Proceeding, 2004 WL 1660351 (Special Master Hastings denied motion seeking discovery from Merck).

It is not reasonable or necessary to obtain samples of the 2011 formulation of HPV vaccine, if they even exist, or the other materials petitioner requested in her discovery motion. Petitioner does not have burden of identifying and proving a specific biological mechanism. Knudsen v. Sec’y of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994). Dr. Moissidis or anyone else who is petitioner’s expert must review petitioner’s medical records and evaluate whether HPV vaccine can cause urticaria and rashes (lasting more than six months), acne vulgaris, panic attacks, anxiety, and dermatographism and, if so, that it did so in this case.

Petitioner’s motion for discovery is **DENIED**.

IT IS SO ORDERED.

July 10, 2017
DATE

/s/ Laura D. Millman
Laura D. Millman
Special Master